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U.S. PATENT DOCUMENTS

Examiner Initials	Document No.	Date MM/DD/YYYY	Name	Classification

	FOREIGN PATENT DOCUMENTS			
Examiner Initials	Document No.	Date	Country	
	WO 99/16873	08/04/1999		
	EP 0 533 838	03/12/1997		7
-	EP 0 931 830	07/03/2001		
	WO 00/022136	20/04/2000		
	WO 03/033692 A2	24/04/2003		
	WO 03/033692 A3	24/04/2003		
	WO 03/099859	04/12/2003		
	WO 98/08856	05/03/1998		

	NON-PATENT LITERATURE DOCUMENTS
Examiner Initials	Author, title of the article, title of the item (book, magazine, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	Ahonen, et al.; Antitumor Activity and Bystander Effect of Adenovirally Delivered Tissue Inhibitor of Metalloproteinases-3 2002, Mol Therapy 5(6): 705-715
	Amin, A., et al.; 9-Nitrocamptothecin as second line chemotherapy for men with progressive, metastatic, hormone refractory prostate cancer: Results of the CALGB 99901 2004, Urol. Oncol. 22(5): 398-403
	Arai, et al.; Gene transfer of Fas ligand induces tumor regression vivo 1997, PNAS 94(25): 13862-13867
	Atadja, et al.; Selective Growth Inhibition of Tumor Cells by a Novel Histone Deacetylase Inhibitor, NVP-LAQ824 2004, Cancer Res. 64(2): 689-695
	Avemann, et al.; Camptothecin, a specific inhibitor of type I DNA topoisomerase, induces DNA breakage at replication forks 1988, Mol. Cell. Biol. 8(8): 3026-3034
	Azzariti, A., et al.; The schedule-dependent enhanced cytotoxic activity of 7-ethyl- 10-hydroxy-camptothecin (SN-38) in combination with Gefitinib (Iressa™,

 ZD1839) 2004, Biochem Pharmacol. 68(1): 135-144
 Balague, C., et al.; Human Papillomavirus E6E7-Mediated Adenovirus Cell Killing:
Selectivity of Mutant Adenovirus Replication in Organotypic Cultures of Human Keratinocytes 2001, J. Virol. 75(16): 7602-7611
Bargou, R.C., et al.; Nuclear localization and increased levels of transcription
factor YB-1 in primary human breast cancers are associated with intrinsic MDR1 gene expression, 1997, Nat. Med. 3(4): 447-450
Barnett, B.G., et al.; <i>Targeted adenoviral vectors</i> 2002, Biochimica Biophysica Acta 1575: 1-14
Binaschi, M., et al.; Relationship between Lethal Effects and Topoisomerase Il- Mediated Double-Stranded DNA Breaks Produced by Anthracyclines with Different Sequence Specificity Mol. Pharmacol. 51(6): 1053-1059
Bischof, M., et al.; <i>Triple combination of irradiation, chemotherapy (pemetrexed), and VEGFR inhibition (SU5416) in human endothelial and tumor cells</i> 2004, Int. J. Radiat. Oncol. Biol. Phys. 60(4): 1220-1232
Boulanger & Blair; Expression and interactions of human adenovirus oncoproteins 1991, Biochem. J. 275: 281-299
Braithwaite & Russell; <i>Induction of cell death by adenoviruses</i> 2001, Apoptosis 6(5): 359-370
Brandt, K.; Cancer Gene Therapy with Tissue Inhibitors of Metalloproteinases (TIMPs) 2002, Curr. Gene Therapy 2(2): 255-271
Braunstein, I., et al.; Human Telomerase Reverse Transcriptase Promoter Regulation in Normal and Malignant Human Ovarian Epithelial Cells 2001 Cancer Res. 61(14): 5529-5536
Bridge & Ketner; Interaction of adenoviral E4 and E1b products in late gene expression 1990, Virology 174(2): 345-353
Camphausen, K., et al.; Enhancement of Xenograft Tumor Radiosensitivity by the Histone Deacetylase Inhibitor MS-275 and Correlation with Histone Hyperacetylation 2004, Clinical Cancer Res. 10(18): 6066-6071
Cantore, M., et al.; Combined Irinotecan and Oxaliplatin in Patients with Advanced Pre-Treated Pancreatic Cancer 2004, Oncology 67(2): 93-97
Cao, G., et al.; Comparison of carcinoembryonic antigen promoter regions isolated from human colorectal carcinoma and normal adjacent mucosa to induce strong tumor-selective gene expression 1998, Int. J. Cancer 78(2): 242-247
Chen, C-Y, et al.; Nucleolin and YB-1 are required for JNK-mediated interleukin-2 mRNA stabilization during T-cell activation 2000, Genes & Development 14(10): 1236-1248
Chung, I., et al.; Use of L-plastin promoter to develop an adenoviral system that confers transgene expression in ovarian cancer cells but not in normal mesothelial cells 1999, Cancer Gene Therapy 6(2): 99-106
Cin; Genomic Changes in Endometrial Polyps Associated with Tamoxifen Show No Evidence for Its Action as an External Carcinogen 1998, Cancer Res. 58(11): 2278-2281
Coulson, J.M., et al.; <i>Tumour-specific arginine vasopressin promoter activation in small-cell lung cancer</i> 1999, British J. Cancer 80(12): 1935-1944
Descamps, et al.; Strategies for cancer gene therapy using adenoviral vectors 1996, J. Mol. Med. 74(4): 183-189
Dobbelstein, M., et al.; Nuclear export of the E1B 55-kDa and E4 34-kDa adenoviral oncoproteins mediated by a rev-like signal sequence 1997 EMBO J.

16(14): 4276-4284
Doronin, et al.; Tumor-Specific, Replication-Competent Adenovirus Vectors Overexpressing the Adenovirus Death Protein 2000, J. Virology 74(13): 6147- 6155
Dyson; The regulation of E2F by pRB-family proteins 1998, N. Genes & Development 12(15): 2245-2262
Efthymiadis, A., et al.; The HIV-1 Tat Nuclear Localization Sequence Confers Novel Nuclear Import Properties 1998, JBC 273(3): 1623-1628
Fribley, A., et al.; Proteasome Inhibitor PS-341 Induces Apoptosis through Induction of Endoplasmic Reticulum Stress-Reactive Oxygen Species in Head and Neck Squamous Cell Carcinoma Cells 2004, Mol. Cell Biol. 24(22): 9695-9704
Friedberg, E.C.; Nuclear targeting sequences 1992, TIBS 17(9): 347
Fueyo, J., et al.; A mutant oncolytic adenovirus targeting the Rb pathway produces anti-glioma effect in vivo 2000, Oncogene 19(1): 2-12
Gadi, et al.; A Long-Acting Suicide Gene Toxin, 6-Methylpurine, Inhibits Slow Growing Tumors after a Single Administration 2003, J. Pharmacol. And Exp. Therapeutics 304(3): 1280-1284
Ganly, I., et al.; Replication and cytolysis of an E1B-attenuated adenovirus in drug-resistant ovarian tumor cells is associated with reduced apoptosis, 2001, Gene Therapy 8(5): 369-375
Gilbert, et al.; Phase I Clinical and Pharmacokinetic Study of Irinotecan in Adults with Recurrent Malignant Glioma 2003, Clinical Cancer Res. 9(8): 2940-2949
Goodrum & Ornelles; Roles for the E4 orf6, orf3, and E1B 55-Kilodalton Proteins in Cell Cycle-Independent Adenovirus Replication 1999, J. Virology 73(9): 7474-7488
Gottesman & Pastan; Biochemistry of multidrug resistance mediated by the multidrug transporter 1993, Annu. Rev. Biochem 62: 385-427
Hajitou, et al.; The antitumoral effect of endostatin and angiostatin is associated with a down-regulation of vascular endothelial growth factor expression in tumor cells 2002 FASEB J. 16(13): 1802-1804
Hallenbeck, P.L., et al.; A Novel Tumor-Specific Replication-Restricted Adenoviral Vector for Gene Therapy of Hepatocellular Carcinoma 1999, Human Gene Therapy 10(10): 1721-1733
Hasan, S., et al.; Transcription coactivator p300 binds PCNA and may have a role in DNA repair synthesis 2001, Nature 410: 387-391
Heise, C., et al.; An adenovirus E1A mutant that demonstrates potent and selective systemic anti-tumoral efficacy 2001, Nature Medicine 6(10): 1134-1139
Heise, et al.; ONYX-015, an E+B gene-attenuated adenovirus, causes tumor- specific cytolysis and antitumoral efficacy that can be augmented by standard chemotherapeutical agents, 1997, Nat. Med. 3(6): 639-645
Helt & Galloway; Mechanisms by which DNA tumor virus oncoproteins target the Rb family of pocket proteins 2003, Carcinogenesis 24(2): 159-169
Holm, P.S., et al.; YB-1 relocates to the nucleus in adenovirus infected cells and facilitates viral replication E2 gene expression through the E2-late promoter, 2002, J. Biol. Chem. 277(12): 10427-10434
Horwitz, M.S.; Adenovirus Immunoregulatory Genes and Their Cellular Targets 2001, Virology 279(1): 1-8

	Howe, J.A., et al.; Evaluation of E1-mutant adenoviruses as conditionally
	replicating agents fro cancer therapy, 2000, Mol. Therapy 2(5): 485-493
	Hu, Z., et al.; Transcriptional Activation of the MDR1 Gene by UV Irradiation. ROLE OF NF-Y AND Sp1 2000, J. Biol. Chem. 275(4): 2979-2985
	Jaboin, et al.; MS-27-275, an Inhibitor of Histone Deacetylase, Has Marked in
	Vitro and in Vivo Antitumor Activity against Pediatric Solid Tumors 2002, Cancer
	Res. 62(21): 6108-6115
	Jans, D.A., et al.; Nuclear targeting signal recognition: a key control point in nuclear transport? 2000 Jun, Bioessays 22(6): 532-44
	Ji, et al.; Induction of Apoptosis and Inhibition of Tumorigenicity and Tumor
	Growth by Adenovirus Vector-mediated Fragile Histidine Triad (FHIT) Gene
	Overexpression 1999, Cancer Res. 59(14): 3333-3339
	Kamiya & Nakazatp; <i>The Expression of P73, P21 and MDM2 Proteins in Gliomas</i> 2002, J. Neurooncology 59(2): 143-149
	Keen, J.C., et al.; A Novel Histone Deacetylase Inhibitor, Scriptaid, Enhances
	Expression of Functional Estrogen Receptor alpha (ER) in ER negative human
	breast cancer cells in combination with 5-aza 2prime-deoxycytidine 2003, Breast Cancer Res. Treat. 81(3): 177-186
	Kim, J.H., et al.; Susceptibility and radiosensitization of human glioblastoma cells
	to trichostatin A, a histone deacetylase inhibitor 2004, Int. J. Radiat. Oncol. Biol. Phys. 59(4): 1174-1180
	Kindler, H.L., et al.; 9-Aminocamptothecin (9-AC) given as a 120-hour continuous
	infusion in patients with advanced adenocarcinomas of the stomach and
	gastroesophageal junction: A phase II trial of the University of Chicago phase II
	consortium 2004, Invest. New Drugs 22(3): 323-327
	Kitazono, et al.; Enhanced Adenovirus Transgene Expression in Malignant Cells
	Treated with the Histone Deacetylase Inhibitor FR901228 2001, Cancer Res.
	61(17): 6328-6330
	Koike, K., et al.; Nuclear translocation of the Y-box binding protein by ultraviolet
	irradiation 1997, FEBS Lett. 417(3): 390-394
	Koyama, et al.; Combined suicide gene therapy for human colon cancer cells
	using adenovirus-mediated transfer of Escherichia coli cytosine deaminase gene
	and Escherichia coli uracil phosphoribosyltransferase gene with 5-fluorocytosine 2000, Cancer Gene Therapy 7(7): 1015-1022
	Lasham, A., et al.; Regulation of the human fas promoter by YB-1, Purα and AP-1
	transcription factors 2000, Gene 252: 1-13
	Le, Q.T., et al.; Phase I Study of Tirapazamine Plus Cisplatin/Etoposide and
	Concurrent Thoracic Radiotherapy in Limited-Stage Small Cell Lung Cancer
	(S0004): A Southwest Oncology Group Study 2004, Clinical Cancer Res. 10(16):
	5418-5424
	Lockett, et al.; Relative efficiency of tumor cell killing in vitro by two enzyme-
÷	prodrug systems delivered by identical adenovirus vectors 1997, Clinical Cancer
	Res. 3(11): 2075-2080
	Lyons, R.H.; <i>Pentapeptide nuclear localization signal in adenovirus E1a</i> 1987, Mol. Cell Biol. 7(7): 2451-2456
	Magnusson, M.K., et al.; Genetic Retargeting of Adenovirus: Novel Strategy
1	Employing "Deknobbing" of the Fiber 2001, J. Virology 75(16): 7280-7289
	Majumdar, A.S., et al.; The telomerase reverse transcriptase promoter drives
	efficacious tumor suicide gene therapy while preventing hepatotoxicity

encountered with constitutive promoters 2001, Gene Therapy 8(7): 568-578
Majumdar, et al.; Efficacy of herpes simplex virus thymidine kinase in combination with cytokine gene therapy in an experimental metastatic breast cancer model 2000, Cancer Gene Therapy 7(7): 1086-1099
Makino, Y., et al.; Structural and functional analysis of the human Y-box binding protein (YB-1) gene promoter 1996, Nucleic Acids Res. 24(10): 1873-1878
McClue, S.J.; In vitro and in vivo antitumor properties of the cyclin dependent kinase inhibitor CYC202 (R-roscovitine) 2002, Int. J. Cancer 102(5): 463-468
Mertens, P.R., et al.; Glomerular Mesangial Cell-specific Transactivation of Matrix Metalloproteinase 2 Transcription Is Mediated by YB-1 1997, JBC 272(36): 22905-22912
Mizuguchi & Hayakawa; Adenovirus vectors containing chimeric type 5 and type 35 fiber proteins exhibit altered and expanded tropism and increase the size limit of foreign genes 2002, GENE 285: 69-77
Nemunaitis, J.J., et al.; Phase I Study of Oral CI-994 in Combination with Gemcitabine in Treatment of Patients with Advanced Cancer 2003, Cancer J. 9: 58-66
Nevins, J.R.; Mechanism of activation of early viral transcription by the adenovirus E1A gene product 1981, Cell 26(2): 213-220
Nicklin, S.A., et al.; Ablating Adenovirus Type 5 Fiber–CAR Binding and HI Loop Insertion of the SIGYPLP Peptide Generate an Endothelial Cell-Selective Adenovirus 2001, Mol. Therapy 4(6): 534-542
Niculescu-Duvaz, et al.; Recent developments in gene directed enzyme prodrug therapy (GDEPT) for cancer 1999, Curr. Opin. Mol. Therapy 1(4): 480-486
Nimmanapalli, R., et al.; Histone Deacetylase Inhibitor LAQ824 Both Lowers Expression and Promotes Proteasomal Degradation of Bcr-Abl and Induces Apoptosis of Imatinib Mesylate-sensitive or -refractory Chronic Myelogenous Leukemia-Blast Crisis Cells 2003, Cancer Res. 63(16): 5126-5135
Oda, Y., et al.; Nuclear expression of YB-1 protein correlates with P-glycoprotein expression in human osteosarcoma 1998, Clin. Cancer Res. 4(9): 2273-2277
Ohga, T., et al.; Direct Involvement of the Y-box Binding Protein YB-1 in Genotoxic Stress-induced Activation of the Human Multidrug Resistance 1 Gene 1998, J. Biol. Chem. 273(11): 5997-6000
Ohga, T., et al.; Role of the Human Y Box-binding Protein YB-1 in Cellular Sensitivity to the DNA-damaging Agents Cisplatin, Mitomycin C, and Ultraviolet Light 1996, Cancer Res. 56(18): 4224-4228
Okamoto, T., et al.; Direct interaction of p53 with the Y-box binding protein, YB-1: a mechanism for regulation of human gene expression 2000, Oncogene 19(54): 6194-6202
Opalka, et al.; Apoptotic Genes in Cancer Therapy 2002, Cell Tissues Organs 172(2): 126-132
Ornelles & Shenk; Localization of the adenovirus early region 1B 55-kilodalton protein during lytic infection: association with nuclear viral inclusions requires the early region 4 34-kilodalton protein 1991, J. Virology 65(1): 424-429
Piganeau, N., et al.; An Allosteric Ribozyme Regulated by Doxycycline 2000, Angew. Chem. Int. Ed. 39(23): 4369-4373
Plumb, J.A., et al.; <i>Pharmacodynamic Response and Inhibition of Growth of Human Tumor Xenografts by the Novel Histone Deacetylase Inhibitor PXD101</i> 2003, Mol. Cancer Ther. 2(8): 721-728

Rajendra, et al., Differential Effects of the Breast Cancer Resistance Protein on the Cellular Accumulation and Cytotoxicity of 9-Aminocamptothecin and 9-Nitrocamptothecin 2003 Cancer Res. 63(12): 3228-3233
Recchia, F., et al.; Multicentre phase II study of bifractionated CPT-11 with bimonthly leucovorin and 5-fluorouracil in patients with metastatic colorectal cancer pretreated with FOLFOX 2004, British J. Cancer 91(8): 1442-1446
Rodriguez, R., et al.; Prostate Attenuated Replication Competent Adenovirus (ARCA) CN706: A Selective Cytotoxic for Prostate-specific Antigen-positive Prostate Cancer Cells 1997, Cancer Res. 57(13): 2559-2563
Rogers, et al.; Killing Epstein-Barr virus-positive B lymphocytes by gene therapy: comparing the efficacy of cytosine deaminase and herpes simplex virus thymidine kinase 1996, Human Gene Therapy 7: 2235-2245
Sato, N., et al.; FR901228, a novel histone deacetylase inhibitor, induces cell cycle arrest and subsequent apoptosis in refractory human pancreatic cancer cells 2004, Int. J. Oncol. 24(3): 679-685
Shibao, K., et al.; Enhanced coexpression of YB-1 and DNA topoisomerase II agr genes in human colorectal carcinomas 1999, Int. J. Cancer 83(6): 732-737
Soff, et al.; Expression of plasminogen activator inhibitor type 1 by human prostate carcinoma cells inhibits primary tumor growth, tumor-associated angiogenesis, and metastasis to lung and liver in an athymic mouse model 1995, J. Clin. Invest. 96(6): 2593-2600
Steegenga, W.T. et al.; The large E1B protein together with the E4orf6 protein target p53 for active degradation in adenovirus infected cells 1998, Oncogene 16(3): 349-357
Stein, U., et al.; Hyperthermia-induced Nuclear Translocation of Transcription Factor YB-1 Leads to Enhanced Expression of Multidrug Resistance-related ABC Transporters 2001, JBC 276(30): 28562-69
Stiewe, et al.; Inactivation of Retinoblastoma (RB) Tumor Suppressor by Oncogenic Isoforms of the p53 Family Member p73 2003, J. Biol. Chem. 278(16): 14230-14236
Su, et al.; Melanoma differentiation associated gene-7, mda-7/IL-24, selectively induces growth suppression, apoptosis and radiosensitization in malignant gliomas in a p53-independent manner 2003, Oncogene 22(8): 1164-1180
Sumantran, et al.; Overexpression of Bcl-xS Sensitizes MCF-7 Cells to Chemotherapy-induced Apoptosis 1995, Cancer Res. 55(12): 2507-2512
Sundararajan, R. & White, E.; <i>E1B 19K Blocks Bax Oligomerization and Tumor Necrosis Factor Alpha-Mediated Apoptosis</i> 2001, J. Virology 75(16): 7506-7516
Swamynathan, S.K., et al.; Role of single-stranded DNA regions and Y-box proteins in transcriptional regulation of viral and cellular genes 1998, FASEB J. 12(7): 515-522
Tollefson, A., et al.; <i>Tumor-Specific, Replication-Competent Adenovirus Vectors Overexpressing the Adenovirus Death Protein</i> 1996, J. Virology 70(4): 2296-2306
Toth, et al.; Radiation increases the activity of oncolytic adenovirus cancer gene therapy vectors that overexpress the ADP (E3-11.6K) protein 2003, Cancer Gene Therapy 10(3): 193-200
Tralhao, et al.; In vivo selective and distant killing of cancer cells using adenovirus-mediated decorin gene transfer 2003, FASEB J. 17(3): 464-466 Tsukada, et al.; An E2F-responsive Replication-selective Adenovirus Targeted to
the Defective Cell Cycle in Cancer Cells: Potent Antitumoral Efficacy but No

 Toxicity to Normal Cell Cancer Res. 62(12): 3438-3447
Vigushin, et al.; <i>Trichostatin A Is a Histone Deacetylase Inhibitor with Potent Antitumor Activity against Breast Cancer in Vivo</i> 2001, Clinical Cancer Res. 7(4): 971-976
Weigel & Dobbelstein; The Nuclear Export Signal within the E4orf6 Protein of Adenovirus Type 5 Supports Virus Replication and Cytoplasmic Accumulation of Viral mRNA 2000, J. Virology 74(2): 764-772
Whittaker, G.R., et al.; <i>Nuclear Import and Export of Viruses and Virus Genomes</i> 1998, Virology 246(1): 1-23
Wilhelm, S.M., et al.; BAY 43-9006 Exhibits Broad Spectrum Oral Antitumor Activity and Targets the RAF/MEK/ERK Pathway and Receptor Tyrosine Kinases Involved in Tumor Progression and Angiogenesis 2004, Cancer Res. 64(19): 7099-7109
Wong, H.K., et al.; Complementary functions of Ela conserved region 1 cooperate with conserved region 3 to activate adenovirus serotype 5 early promoters, 1994, J. Virology 68(8): 4910-4920
Wybranietz, W.A., et al.; Enhanced suicide gene effect by adenoviral transduction of a VP22-cytosine deaminase (CD) fusion gene 2001, Gene Therepy 8(21): 1654-1664
Yamaguchi, et al.; Enhancement of thymidine kinase-mediated killing of malignant glioma by BimS, a BH3-only cell death activator 2003, Gene Therapy 10(5): 375-385
Yoneda, Y.; How Proteins Are Transported from Cytoplasm to the Nucleus 1997, J. Biochem (Tokyo) 121(5): 811-817
Zambetti, G.P., et al.; A comparison of the biological activities of wild-type and mutant p53 1993, FASEB J. 7(10): 855-865
Zhang & Degroot; Gene Therapy of a Rat Follicular Thyroid Carcinoma Model with Adenoviral Vectors Transducing Murine Interleukin-12 2003, Endocrinology 144(4): 1393-1398
Zhang, et al.; Adenoviral-mediated Retinoblastoma 94 Produces Rapid Telomere Erosion, Chromosomal Crisis, and Caspase-dependent Apoptosis in Bladder Cancer and Immortalized Human Urothelial Cells but not in Normal Urothelial Cells 2003, Cancer Res. 63(4): 760-765
Zhang, et al.; Identification of Human Uroplakin II Promoter and Its Use in the Construction of CG8840, a Urothelium-specific Adenovirus Variant That Eliminates Established Bladder Tumors in Combination with Docetaxel 2002, Cancer Res. 62(13): 3743-3750
Zhang, et al.; Monogene and Polygene Therapy for the Treatment of Experimental Prostate Cancers by Use of Apoptotic Genes bax and bad Driven by the Prostate-Specific Promoter ARR ₂ PB 2002, Hum. Gene Ther. 13(17): 2051-2064

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